



- Warning : Carefully read the enclosed instructions prior to use.
- Attenzione : Leggere attentamente le istruzioni allegate prima dell'uso.
- Attention : Lire attentivement les instructions jointes avant l'utilisation.
- Achtung : Vor der Benutzung die beiliegenden Hinweise aufmerksam lesen.
- Advertencia : Antes de uso, lea cuidadosamente las instrucciones que se incluyen.

CUSTOMER LETTER (OUTSIDE USA ONLY)
URGENT: MEDICAL DEVICE FIELD CORRECTION
Dideco *Electa* and *Compact* Family of Autotransfusion Wash Sets

August 07, 2006

Dear Sorin Group Customer,

We have received reports of difficulty in inserting the disposable wash set bowl used with the Dideco *Electa* and *Compact* family of autotransfusion machines. The difficulty is due to a manufacturing process issue, which has been corrected. We wish to alert you to the issue, and to remind you that proper bowl insertion is essential to the safe and effective use of the machine. We would remind you that, as noted in the Instructions for Use ('IFUs') if a bowl cannot be inserted properly, do not use it. Please return it to us immediately for a non-cost replacement.

If a bowl cannot be inserted in accordance with the IFUs, there is a risk that the bowl's rotating seal could deteriorate during centrifuging, releasing particulate into the processed blood.

These wash set bowls are shipped as sterile stand alone wash sets, or as part of autotransfusion kits. Following are the affected lot number(s).

Starting from lot# 0601230037 the items listed below may show difficulties to be inserted

code	Product	KIT	code	Product	KIT
4125	740C/125	Compact Wash Set	4162M	740E/55	Electa Wash Set
4126	740C/175	Compact Wash Set	4163M	740E/125	Electa Wash Set
4127	740C/225	Compact Wash Set	4164M	740E/175	Electa Wash Set
4149	740C/55	Compact Wash Set	4165M	740E/225	Electa Wash Set
4145	740C/125	Compact ATS Kit	4167M	745E/55	Electa ATS Kit
4146	740C/175	Compact ATS Kit	4168M	745E/125	Electa ATS Kit
4147	740C/225	Compact ATS Kit	4169M	745E/175	Electa ATS Kit
4148	740C/55	Compact ATS Kit	4170M	745E/225	Electa ATS Kit

Please follow the attached instructions for all wash set bowls in order to avoid the risk of patient injury. We remind you that the use of a 40 micron micro aggregate filter when re-infusing collected blood is strongly recommended. Any units failing the attached instructions should not be used and should be returned to your local Sorin Group representative for no-charge replacement product.

If you have any questions, please contact your local Sorin Group Customer Service. We apologize for the inconvenience this may cause you and appreciate your understanding and cooperation on this issue.

Sincerely,

 Marco Mantovani
 Director, RA/QA
 Sorin Group Italia S.r.l.

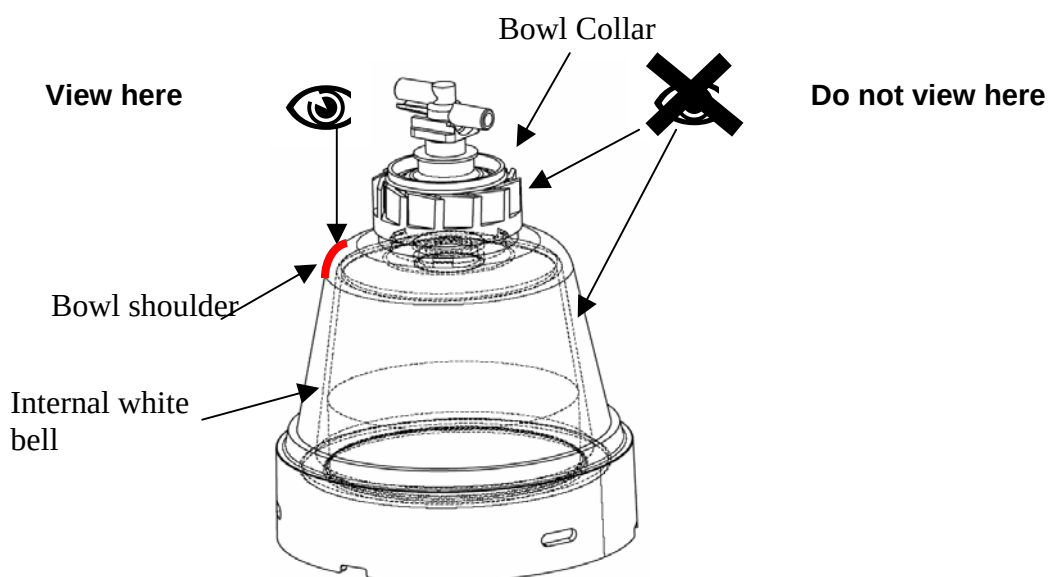


URGENT: MEDICAL DEVICE FIELD CORRECTION

Dideco *Electa* and *Compact* Family of Autotransfusion Wash Sets

Dideco Autotransfusion Wash Set Bowl – Executive Summary
Ensuring Proper Insertion of the Dideco Wash Set Bowl

1. Viewing the bowl from directly above, insert the bowl using two hands;
2. Press firmly until you hear a distinct ‘snap’ or ‘click’ sound as the bowl connects flush with the centrifuge plate. If this sound is not obtained, remove and reattempt insertion, rotating bowl 120°. If still not inserted correctly, do not use the bowl, replace wash set and return to your local Sorin Group representative;
3. Rotate the bowl manually to ensure bowl rotates properly on its axis: ensure proper alignment by viewing from directly above ‘shoulder’ of bowl (as per figure below). If not rotating correctly, do not use the bowl, replace wash set and return to your local Sorin Group representative;
4. Rotate using machine centrifuge. If abnormal noise or vibration occurs, do not use the bowl, replace wash set and return to your local Sorin Group representative.



URGENT: MEDICAL DEVICE FIELD CORRECTION

Dideco *Electa* and *Compact* Family of Autotransfusion Wash Sets

Dideco Autotransfusion Wash Set Bowl Instructions

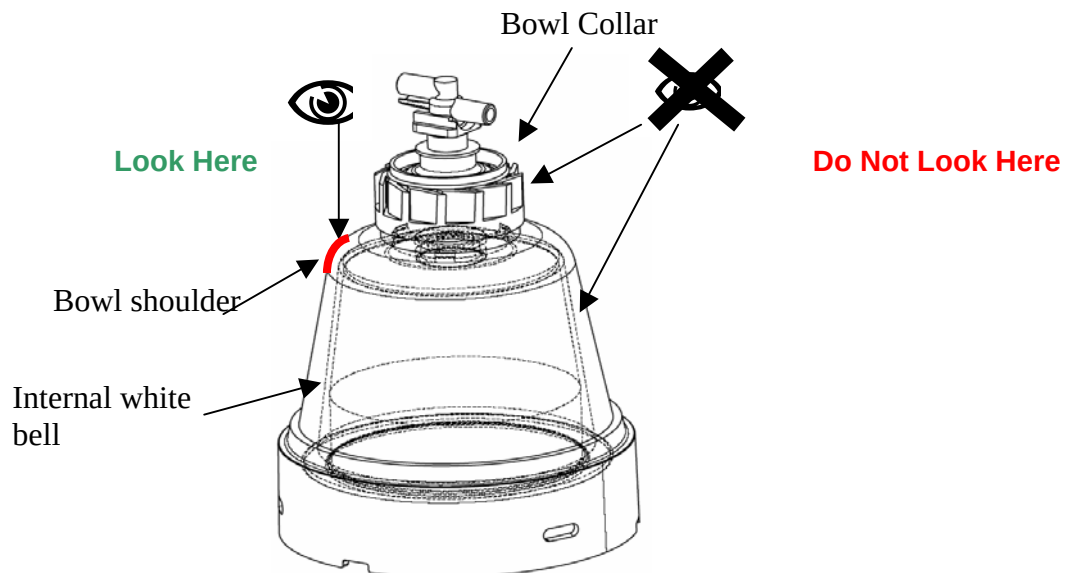
PURPOSE:

This verifies proper insertion of the Dideco wash set bowl in conjunction with the Field Correction letter dated August 07th, 2006.

PRINCIPLE:

A wash set is setup according to standard 'Instructions for Use' (IFU) procedures. The empty bowl is first spun manually and then spun automatically. The bowl is carefully observed for abnormal noise, abnormal vibration or wobbling, abnormal rotation or spinning. You will recognize abnormal vibration or wobbling if the bowl has not been inserted correctly and the bottom of the bowl does not fit flush with the centrifuge plate. You will recognize when the bowl is inserted and positioned properly through a 'snap' or 'click' noise detected as the bowl fits flush with the centrifuge plate.

The rotation path of the bowl should be observed by viewing the 'shoulder' of the rotating bowl from directly above. The figure below shows the correct manner in which to observe the rotation of the bowl.



IF, DURING MANUAL TURNING, ABNORMAL ROTATION IS OBSERVED DO NOT USE THE BOWL, REPLACE WASH SET AND RETURN TO YOUR LOCAL SORIN GROUP REPRESENTATIVE

IF DURING CENTRIFUGAL ROTATION ABNORMAL NOISE, VIBRATION OR WOBBLING IS DETECTED, DO NOT USE THE BOWL, REPLACE WASH SET AND RETURN TO YOUR LOCAL SORIN GROUP REPRESENTATIVE.

PROCEDURE:

1. Follow 'Instructions for Use' for correct wash set bowl insertion. The main extracts from the IFU are listed below.

Electa:

Instructions for Use: Chapter 5 ('Operating Instructions') sets out the specific instructions regarding 'Fitting the Washing Set':

5. Keep the three indentations (fig. 5.19, no.1) on the bowl base ring aligned with the corresponding metal disks on the centrifuge rotating plate and press the bowl fully downwards, ensuring that the axis is perpendicular to the rotating plate.

Remove the protective spacer from the upper part of the bowl (fig. 5.19, no. 2).

Manually rotate the bowl to check for eccentricity. If necessary, remove the bowl and repeat the installation.

Compact:

User Manual: Chapter 4 ('Operating Instructions') sets out the specific instructions regarding 'Fitting the Disposable Sets':

3. Remove the bowl from the container and remove the protective collar from the top of the bowl. Locate the three reference pins on the base of the bowl and fit it into the centrifuge well, aligning these reference pins with those on the centrifuge rotary plate (Fig. 4.9). The bowl must be fitted keeping its axis perpendicular to the rotary plate. After the fitting has been carried out, rotate manually to ensure that rotation is non-eccentric. If eccentricity is detected, remove the bowl and repeat the fitting procedure.

Note:

- a) The wash set bowl will fit correctly only when adequate pressure is used thereby ensuring the bottom of the bowl fits 'flush' with the bottom of the machine centrifuge plate.
- b) Use two hands to press down on the body of the bowl until a 'snap' or 'click' is heard indicating that the bottom of the bowl touches the centrifuge plate evenly.
- c) If this sound is not obtained, remove and reattempt insertion, rotating bowl 120°. If still not inserted correctly, do not use the bowl, replace wash set and return to your local Sorin Group representative.

2. Manually spin the bowl and observe rotation per above figure. Complete set-up of roller pump and clamps.

Note:

- a) For *Electa* press the 'new procedure' key to complete loading the disposable. If the bowl size is not properly read, this may also indicate improper bowl insertion. Remove the bowl and re-attempt insertion. If still not inserted correctly, do not use the bowl, replace wash set and return to your local Sorin Group representative.

3. Press the STAND BY and the PRIME key in sequence (the centrifuge starts rotating while the pump is stopped). Observe the bowl rotation for around 20 seconds then press STOP. If the bowl shows abnormal vibration, wobbling and/or abnormal noise do not use the bowl, replace wash set and return to your local Sorin Group representative.

IF DURING MANUAL ROTATION ABNORMAL SPINNING IS OBSERVED DO NOT USE THE BOWL, REPLACE WASH SET AND RETURN TO YOUR LOCAL SORIN GROUP REPRESENTATIVE.

IF DURING CENTRIFUGAL ROTATION ABNORMAL NOISE, VIBRATION OR WOBBLING IS DETECTED, DO NOT USE THE BOWL, REPLACE WASH SET AND RETURN TO YOUR LOCAL SORIN GROUP REPRESENTATIVE.

4. If the wash set bowl passes these instructions continue with normal operation.

5. If the wash set fails these instructions DO NOT USE THE BOWL, REPLACE WASH SET AND RETURN TO your local Sorin Group representative